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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/167,705

10/06/98

SCHMIDT

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55873JPWJML

HM22/0830

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EXAMINER

ANDRES, J

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

17
08/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Applicati n N .

09/167,705

Applicant(s)

SCHMIDT ET AL.

Examiner

Janet L Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10- 53, 55-72 is/are pending in the application.
- 4a) Of the above claim(s) 10-46, 53 and 69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47-52, 55-68 and 70-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

RESPONSE TO AMENDMENT

1. Applicant's amendment filed 21 June 2001 in paper no. 16 is acknowledged. Claims 10-47-52, 53, and 55-72 are pending in this application. Applicant states that claims 48, 49, 51, and 52 are cancelled but Applicant has not requested this cancellation. New claims 70-72 are added. Claims 10-46, 53, and 69 are withdrawn from consideration as being drawn to a non-elected invention. Claims 47, 50, 55-68, and 70-72 are under consideration in this action.
2. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

3. The objection to the title is withdrawn in response to Applicant's amendment.
4. The rejection of claims 47, 50, and 55-68 as indefinite in the recitation of "RAGE" and "EN-RAGE" is withdrawn in response to Applicant's arguments.

Claim Rejections Maintained/New Grounds of Rejection

5. The specification is newly objected to because there is no sequence identifier for the sequence presented in figure 5.
6. The rejection of claims 49, 51, and 52 under 35 U.S.C. 112, first paragraph, of claims 48, 49, 51, and 52 under 35 U.S.C. 112, second paragraph, and of claims 48, 49, 51, and 62 under 35 U.S.C. 103(a) are maintained of record because these claims have not in fact been cancelled.
7. Claim 50 is newly objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or

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rewrite the claim(s) in independent form. Claim 50 depends from claim 47 but encompasses EN-RAGE peptides, which are not within the scope of claim 47 as amended.

8. The rejection of claims 47, 50, and 55-68 under 35 U.S.C. 112, first paragraph as lacking enablement commensurate with the scope of the claims is maintained and newly applied to claims 70-72. These claims still encompass peptides derived from EN-RAGE or sRAGE. The Examiner notes that, while claims 70-72 further define the encompassed antibodies, they do not limit the claimed method to one using antibodies. As written, they encompass methods using EN-RAGE or sRAGE peptides. As stated in the previous office action, Applicant has not provided guidance sufficient for one of skill in the art to make and use such peptides. There is no information as to the regions of either protein that are important for binding that would allow one of skill to devise peptides that would interfere with such binding. No "ligand-binding domains" as claimed in claim 50 are set forth in the specification or provided by the prior art. Thus without further guidance as to the structural and functional features of inhibitory peptides, it would require undue experimentation for one of skill in the art to make and use the invention as broadly claimed.

9. The rejection of claims 47, 50, and 55-68 under 35 U.S.C. 112, first paragraph, as lacking written description is similarly maintained and newly applied to claims 70-72. As stated in the previous office action, no common structural or functional features of molecules inhibiting RAGE/EN-RAGE interaction, including inhibitory peptides, are set forth in the specification. No regions or characteristics, such as binding domains, of either protein that would serve to identify a genus of inhibitors are set forth. Thus one skilled in the art would not conclude that Applicant

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was in possession of the claimed genus of peptide inhibitors affecting RAGE/EN-RAGE interaction.

10. The rejection of claims 47, 50, and 55-68 under 35 U.S.C. 103 is maintained. Applicant argues that the prior art does not fairly suggest a role for RAGE in inflammation. However, Morser et al., in column 4, lines 48-50, clearly teaches that AGEs, ligands for RAGE, produce inflammation via receptor-mediated pathways as well as by other means. Morser et al. further teaches, in lines 54-60, that, because of these effects of AGEs, it is valuable to block AGE/RAGE interactions. Neither Morser et al. nor the other references of record teach EN-RAGE. However, use of anti-RAGE antibodies and s-RAGE to inhibit inflammation, as instantly claimed, does not rely on effects on or by EN-RAGE. Thus sufficient motivation for one of ordinary skill to use s-RAGE or anti-RAGE antibodies is provided by Morser et al., since this reference teaches that RAGE ligands cause inflammation in a receptor-mediated fashion and explicitly states that compositions that act with AGE receptors have therapeutic use.

NO CLAIM IS ALLOWED.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 305-3014 or (703) 308-4242.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
August 29, 2001


YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600